JAN 15 2013

Section III 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K123004

1. Date of Submission: September 17, 2012

2. Sponsor
   MIRA LASERS LLC
   10340 Pleasant Street, Noblesville, IN 46060

   Contact Person: Chad Playford
   Position: President
   Tel: 888-546-6472
   Fax: 317-674-1033
   Email: Chad@miralasers.com

3. Submission Correspondent
   Ms. Diana Hong & Mr. Lee Fu
   Mid-Link Consulting Co., Ltd
   P.O. Box 237-023, Shanghai, 200237, China
   Tel: +86-21-22815850
   Fax: 240-238-7587
   Email: info@mid-link.net

4. Proposed Device Identification

   Proposed Device Name: MIRA LASERS
   Proposed Device Model: ZENO 2, ZENO 4
   Common Name: Laser System

   Classification: 2
   Product Code: GEX
   Classification Name: powered laser surgical instrument
   Regulation Number: 21 CFR 878.4810
   Review Panel: General and Plastic Surgery

   Intended Use Statement:

The MIRA LASERS is indicated for incision, excision, hemostasis, coagulation and vaporization of soft tissue including the following indications:

- Excision and Incision Biopsies
- Hemostatic assistance
- Treatment of Apthous Ulcers
- Frenectomy
- Frenotomy
- Gingival Incision and Excision
- Gingivectomy
- Gingivoplasty
- Incising and Draining of Abscesses
- Operculectomy
- Oral Papillectomy
- Removal of Fibromas
- Soft Tissue Crown Lengthening
- Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)
- Tissue retraction for Impression
- Vestibuloplasty
- Laser assisted whitening/bleaching of teeth
- Light activation for bleaching materials for teeth whitening

5. Predicate Device Identification

510(k) Number: K113212
Product Name: Dental Laser Therapy System
Manufacturer: China Daheng Group, Inc.

510(k) Number: K083142
Predicate Device Name: Picasso™
Manufacturer: AMD LASERS™, LLC

6. Device Description

The proposed devices, MIRA LASERS ZENO 2 and MIRA LASERS ZENO 4, are new device for 510(k) submission and share the same indication for use and safety compliance, similar design features and functional features with the predicate device.

The proposed device are designed to be compact, portable, reliable and user-friendly. It provides the practitioner with a versatile instrument for applications ranging from excisions and vaporization of tissues to periodontal treatments and tooth whitening. The MIRA LASERS at 810nm are delivered through a flexible optical fiber, or fixed disposable tip. The systems may be utilized for a wide variety of dental surgical and cosmetic procedures.

The proposed devices include two models, the difference of the two models is only laser power, the laser power of ZENO 2 is 0.6W/1.2W/1.8W, and the laser power of ZENO 4 is 1.0w/2.0/3.5W.

The MIRA LASERS are contained within a compact lightweight plastic/metal housing and consists of a laser diode assembly with a self-contained cooling system, a slim battery pack, front panel display all connected to a circuit board, which controls laser output power and other system parameters for laser proper functioning.

The proposed device includes two different working modes, which are continuous wave and 20Hz pulse.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1: 1988 +A1:1991+A2:1995, Medical Electrical Equipment – Part 1: General requirements for safety.
IEC 60601-1-2: 2001 + A1:2004, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests
IEC 60601-2-22: 2007, Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
IEC 60825-1:2007, Safety of laser products - Part 1: Equipment classification, and requirements

8. Substantially Equivalent Conclusion

The proposed device, MIRA LASERS, is determined to be Substantially Equivalent (SE) to the predicate devices, Dental Laser Therapy System (K113212) and Picasso™ (K083142), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

MIRA Lasers, LLC
% Mid-Link Consulting Company, Limited
Ms. Diana Hong
General Manager
P.O. Box 237-023
Shanghai, China 200237

January 15, 2013

Re: K123004
Trade/Device Name: MIRA LASERS ZENO 2/MIRA LASERS ZENO 4
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 21, 2012
Received: December 10, 2012

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K123004

Section II Indications for Use

510(k) Number: K123004

Device Name: MIRA LASERS ZENO 2/ MIRA LASERS ZENO 4

Indications tor Use:

The MIRA LASERS is indicated for incision, excision, hemostasis, coagulation and vaporization of soft tissue including the following indications:

- Excision and Incision Biopsies
- Hemostatic assistance
- Treatment of Apthous Ulcers
- Frenectomy
- Frenotomy
- Gingival Incision and Excision
- Gingivectomy
- Gingivoplasty
- Incising and Draining of Abscesses
- Operculectomy
- Oral Papillectomy
- Removal of Fibromas
- Soft Tissue Crown Lengthening
- Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)
- Tissue retraction for Impression
- Vestibuloplasty
- Laser assisted whitening/bleaching of teeth
- Light activation for bleaching materials for teeth whitening

[XX] PRESCRIPTION USE	OVER-THE-COUNTER USE
(Part 21 CFR 801 Subpart D)	(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.01.15 13:59:17 -05'00'

(Division Sign-Off)
Division of Surgical Devices
510(k) Number___K123004_____